# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH Day | Month | Year | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET Day | Month | Year |
|---|---|---|---|---|---|---|---|---|---|---|
| PRIVACY | HONDURAS | | PRIVACY | | 96 Years | Female | 93.00 kg | | MAY | 2025 |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Pulmonary fibrosis [Pulmonary fibrosis]
Low sodium [Hyponatremia]
Acute bronchitis [Acute bronchitis]
Fluid retention [Fluid retention]
Kidney problems [Kidney disorder]

Case Description: This solicited case was received from a consumer regarding a patient participating in study with protocol IC4-05520-001-HND (Improve adherence to treatments) in HONDURAS.

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release

**(Continued on Additional Information Page)**

| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION |
|---|---|
| #1 ) 1 DF, qd | #1 ) Oral use |

20. DID REACTION ABATE AFTER STOPPING DRUG? ☒ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE
#1 ) Hypertension (Hypertension)

| 18. THERAPY DATES(from/to) | 19. THERAPY DURATION |
|---|---|
| #1 ) 2020 / 13-JUL-2025 | #1 ) Unknown |

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 ) Losartan (Losartan) ; 2015 / Ongoing
#2 ) Paxil (Piroxicam) ; 2011 / Ongoing

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| 2015 to Ongoing | Historical Condition | Hypertension (Hypertension) |
| Unknown to Ongoing | Historical Condition | Anxiety depression (Depression) |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 0201192800274
Study ID: IC4-05520-001-HND*

24b. MFR CONTROL NO.
**S25010747**

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
21-JUL-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25010747

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

The patient was a 96-year-old female (ID; 0201192800274, Weight :93 kg, Height: 163 cm) with a medical history of Hypertension since 2015. And Depression and anxiety since an unknown date.

The patient has been treated with INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (1 tablet daily, orally) since 2020 to 13-Jul-2025 for Hypertension.

Other concomitant treatments included: Losartan (100 mg daily, orally) since 2015 for Hypertension and Paxil (1 mg daily, orally) since 2011 for Depression and anxiety.

No other concomitant treatment was reported, if any.

On 13-Jul-2025, she experienced Low sodium (119 mmol/l), Pulmonary fibrosis and Acute bronchitis. Due to this, the patient was hospitalized from 13-Jul-2025 to 19-Jul-2025.
The intensity of the events was not obtained. The Pulmonary fibrosis and Acute bronchitis. They gave her a lot of medication to raise her sodium (no names were obtained).
On 13-Jul-2025, she experienced Pulmonary fibrosis and Acute bronchitis, the intensity of the event was not obtained. Due to this, the patient was hospitalized from 13-Jul-2025 to 19-Jul-2025. She did not relate Pulmonary fibrosis and Acute bronchitis to INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32.
Since May -2025, she experienced Fluid retention, she did not relate it to INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32, She related it to kidney problems that were diagnosed on that same date (did not know exact dates).
Treatment of the reaction (Fluid retention): Since May-2025 she took Furosemida 40 mg, 1 tablet and half, daily orally.
Action taken regarding INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32: Discontinued,
On 13-Jul-2025 doctor changed INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 to Amlodipina 10 mg, 1 tablet daily, orally.

Outcome: Low sodium: Recovered, Pulmonary fibrosis: Unknown, Acute bronchitis: Unknown, Fluid retention and Kidney problems: Not Recovered.

Consent to contact the doctor was not obtained.

Reporter assessment: Related for low sodium. Not related for all other events. Serious for Low sodium, pulmonary fibrosis and acute bronchitis because it leads to hospitalization.

Case Comment: Renal disorder, Fluid retention, Bronchitis and Pulmonary fibrosis are unlisted, and Hyponatremia is listed as per RSI of INDAPAMIDE. Considering the role of concomitant medication (piroxicam may cause hyponatremia), diagnosed renal disorder may causing Fluid retention with missing information (definitive therapy and event dates, outcome, investigations) the causal role is possible for Renal disorder, Fluid retention and Hyponatremia while not related for Bronchitis and Pulmonary fibrosis.

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 1 | 13-JUL-2025 | Blood sodium<br>Positive | 119 mmol/l | 145<br>135 |

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) INDAPAMIDE 1.5MG/AMLODIPINE 5MG-F-32 (INDAPAMIDE 1.5 mg, AMLODIPINE 5 mg) Modified-release tablet; Regimen #1 | 1 DF, qd; Oral use | Hypertension (Hypertension) | 2020 / 13-JUL-2025; Unknown |